Diclectin's effectiveness for morning sickness: Report

In the latest issue of the *American Journal of Obstetrics and Gynecology*, a group of American and Canadian researchers report on the effectiveness of Diclectin (the delayed-release formulation of doxylamine and Vitamin B6) for morning sickness.

Morning sickness affects up to 80% of pregnant women, and many of them need relief from their symptom to be able to function at home and at work. The only drug ever approved by the FDA for morning sickness was Bendectin, which was similar to the presently tested Diclectin. Bendectin was removed from the American market in 1983 due to litigations claiming it caused birth defects.

Large studies involving over 200 000 pregnant women and their children refuted the claim of foetal risk, ar two FDA committees concurred that Bendectin was safe. Over the ensuing years, American courts rejecte all claims of malformations against the drug manufacturer. After its removal from the American market, a Quebec-based Canadian company, Duchesnay, kept producing the drug in Canada under the name Diclectin, where it has been safely and effectively used for over 30 years.

Morning sickness

"We are very pleased that this study adds to the extensive information available on the efficacy and matern safety of Diclectin", stated Éric Gervais, executive vice-president of Duchesnay. "Our product has been available on the Canadian market for over three decades as the only approved safe and effective treatmer for nausea and vomiting of pregnancy, commonly referred to as morning sickness. Duchesnay is committe to using this wealth of clinical information to bring Diclectin to the United States market. Currently, there is r approved product in the US for the treatment of this medical condition, forcing pregnant women and their healthcare professional to seek products whose safety has not been studied to such an extent."

The present study, conducted as part of the FDA submission for Diclectin, was carried out in three univers centres in the US: University of Pittsburgh, Texas (Galveston), and Georgetown (Washington DC). All three centres belong to the National Institute of Child and Human Development from the Obstetric Pharmacolog Unit Network.

'A great moment'

"Having a role in making this treatment for nausea and vomiting of pregnancy is a great moment for me an the entire team. It will be one of my most significant professional accomplishments." stated Gary D.V. Hankins, MD, Co-Principal Investigator, University of Texas Medical Branch, Galveston, Texas.

A total of 280 pregnant women with morning sickness were randomised to receive either Diclectin or a similar appearing Placebo. The group receiving Diclectin experienced greater improvement of morning sickness symptoms and quality of life, and shorter loss of time from work. Significantly more women receiving Diclectin asked to continue it after the two-week trial, as compared to the Placebo group.

"With the very wide maternal-foetal safety record of this drug combination, unmatched by any previous dru on the market, we hope that very soon American women will benefit from a safe and effective drug for morning sickness after 30 years of being orphaned from such medication" said Dr. Gideon Koren, the stu

lead author and the director of the Motherisk Program in Toronto, which is a world-leading centre for researching and evaluating drug safety in pregnancy.

Source: Duchesnay Inc.